

**JUN - 8 2001**

## **510K Summary of Safety and Efficacy**

**1. Sponsor Name**

**Manufacturer:**

Cardiac MRI, a subsidiary of Magna Lab, Inc.  
6800 Jericho Turnpike  
Suite 120W  
Syosset, New York 11791

**Primary Contact/Applicant:**

MedSource Technologies, Newton Inc  
150 California Street  
Newton, Massachusetts 02458  
Telephone: (617) 964-9100 Fax: (617) 964-2660

**Secondary Contact:**

Jonathan S. Kahan  
Hogan & Hartson L.L.P.  
555 Thirteenth Street, N.W.  
Washington, DC 2004-1109  
Telephone: (202) 637-5794 Fax: (202) 637-5910

**2. Device Name**

Proprietary Name: Cardiac View 2001 Surface Coil  
Common/Classification Name: Accessory to Magnetic Resonance  
Device, 21CFR 892.1000

**3. Identification of Predicate or Legally Marketed Device**

The Cardiac MRI Surface Coil is substantially equivalent to the following devices:

Phased Array Flexible Cardiac Coil	K984588
Insight 7000 Phased Array Torso Coil	K972340
MAI Quadrature and Phased Array Flex Coil	K954190

**4. Device Description**

The Cardiac View 2001 Surface Coil is a receive only coil. The coil consists of circuitry and electronic components enclosed in a water resistant covering.

The mechanical design allows the coil to be used on patients of varying size. The design of the coil enables it to provide close proximity to the anatomy to be imaged maximizing spatial and contrast resolution while maintaining patient comfort. The coil has been designed for multiple uses.

5. Indications For Use

The Cardiac View 2001 Surface Coil is a receive only coil to be used with the General Electric Signa® CV/i 1.5T MRI scanner. The coil is intended to facilitate complete MR imaging of the heart and associated structures in the thoracic regions of the body.

6. Performance Testing

The Cardiac View 2001 Surface Coil has been tested for the following characteristics:

- Possibility of excessive RF heating
- Imaging performance

Studies demonstrate that there is no evidence of excessive RF heating over time when the Cardiac View 2001 Surface Coil is tested using a test protocol that is representative of clinical conditions. Imaging performance data demonstrates that the Cardiac View 2001 Surface Coil is capable of producing uniform, quality images.

7. Conclusions

This pre-market submission has demonstrated substantial equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN - 8 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Cardiac MRI  
% Ms. Lynn Carter  
Senior Quality Assurance Engineer  
Medsource Technologies, LCC.  
150 California Street  
NEWTON MA 02458

Re: K010802  
Cardiac View Model 2001 Surface Coil  
Dated: March 14, 2001  
Received: March 16, 2001  
Regulatory Class: II  
21 CFR 892.1000/Procode: 90 MOS

Dear Ms. Carter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure (s)

**Section B. Indications for Use Statement**

**Applicant:**

MedSource Technologies, Newton Inc  
150 California Street  
Newton, Massachusetts 02458  
Telephone: (617) 964-9100 Fax: (617) 964-2660

**Device Name:**

Cardiac View 2001 Surface Coil

**510(k) Number (if known):**

K010802

**Indications for Use:**

The Cardiac View 2001 Surface Coil is a receive only coil to be used with the General Electric Signa® CV/i 1.5T MRI scanner. The coil is intended to facilitate complete MR imaging of the heart and associated structures in the thoracic regions of the body.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_

Edward A. Segerson  
(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number

K010802